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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,358	09/16/2003	Sang Yup Lee	Q77446	2373

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,358

Applicant(s)

LEE ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The Amendment filed on Feb.17, 2006 is acknowledged. Claims 6-14 have been amended. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Claims 6-14 are pending and under examination.

DETAIL ACTION

1. Objections

1.1. Claims

Objections to claims 6-14 have been withdrawn, because the claims have been amended. Claims 1-14 were objected to for using the noun "bacteria" as meaning "bacterium", which is a singular form of this noun in English.

2. Rejections

2.3. 35 USC section 112, second paragraph

Rejection of claims 7 and 9-10 made under 35 U.S.C. 112, second paragraph, in the Office action of 12/02/05 (previous action) is withdrawn, because the claims have been amended.

2.4. 35 USC section 112, first paragraph

Written description

Claim 7, and 9-10 were rejected in Office action of 12/02/05 as containing a new matter. This rejection is now withdrawn, because the claims have been amended.

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Claims 6-14 remain rejected because they are directed to an extremely large genus of transformed bacteria and methods of their use, wherein the scope of said genus encompasses:

- a) any known and unknown bacterium which lacks a functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

Applicants disclose only two species of the claimed genus, i. e.:

- 1) *E. coli* wherein the *fadB* gene was deleted by Applicants, and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced, and
- 2) *E. coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced.

Applicants do not disclose bacterial cells used for transformation except for *E. coli*. Also any gene whose origin is different than stated under 1) and 2) was not involved in manipulations. *E. coli* and its *fadB* and *maoC* genes do not provide identifying characteristics of enormous genus of bacteria and their *fadB* and *maoC* genes. Similarly, PHA synthase gene *phaC2_{Ps}* of *Pseudomonas* species used by Applicants does not provide identifying characteristics of the whole genus of PHA genes from all natural and man-made sources. In conclusion, one skilled in the art is not convinced that at the time the application was filed applicants were in possession of the

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broadly claimed invention.

Scope of enablement

Claim 6-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

- 1) *E. coli* wherein the *fadB* gene was deleted by applicants, and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced,
- 2) *E. coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced,

and a method of their use for production of PHA, does not reasonably provide enablement for

- a) any known and unknown bacterium which lacks a functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of the claims encompasses all bacteria and all PHA synthase genes, from any natural and man made sources. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher,

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166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompass engineered bacterium, and method of its use, wherein said bacterium is

- a) any known and unknown bacterium which lacks its own functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

While methods of engineering microorganisms for production of chemicals are well developed and skills of artisans high, no one is able to make the claimed invention without Applicants instruction as to the species of bacterium to be used for transformation, teachings regarding the structure of its *fadB* gene, or a mutant of said bacteria having *fadB* gene inactivated. Furthermore, one skilled in the art is unable to make the claimed invention without instructions regarding the structure of PHA synthase gene that is to be used for transformation and the way of performing said transformation. Provision of transformants of

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- 1) *E. coli* wherein the *fadB* gene was deleted by applicants, and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced, and
- 2) *E. coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species introduced,

does not provide the necessary guidance for engineering the broadly claimed transformants. While enablement is not precluded by the necessity for routine screening, if a large amount of experimentation is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed method produced a desired product. One skilled in the art cannot produce a bacterium characterized as:

- a) any known and unknown bacteria which lacks its own functional *fadB* gene and is transformed to comprise SEQ ID NO:1, and
 - b) wherein said bacteria is transformed with a PHA synthase gene from any natural or man-made source, because it is out of routine experimentation and has a low probability of success absent teaching of representative number of species of the species of bacteria and structure of PHA synthase genes to be used for transformation.
- The low probability of success is based in the high degree of unpredictability in the art. There is a high degree of unpredictability for altering bacteria with an expectation of obtaining a bacterium having the desired characteristics, particularly in view of astronomical number of bacteria and thus their PHA synthase and *fadB* genes. One

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skilled in the art needs also further instruction as to the details of introduction of any PHA gene to any bacterium, as successful expression of the PHA gene depends at least on the type of expression vector used and the codon usage by the host bacterium. One skilled in the art concludes that without a further guidance on the part of Applicants in regards to detailed instructions as to the species of bacteria, structure of PHA synthase gene and methods of introducing it to said bacterial species, experimentation left to those in the art is improperly extensive and undue.

Response to Applicants' arguments

Traversing rejection of claims 6-14 under 35 USC, section 112, first paragraph, Applicants argue that

- 1) E. coli is a representative example of bacterium;
- 2) the subject matter of the claims need not be described literally, and the patent need not teach, and preferably omits what is well known in the art.

Applicants arguments were fully considered but are found not persuasive for the following reasons.

Regarding point 1) there is nothing as "a representative example of bacterium". The fact that E. coli is the best studied, and the most frequently used in biotechnology, does not mean that it identifies all the species of bacteria including astronomical number their specific features. Is E. coli ~~is~~ a representative of any Thermophilus species, for example?

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Regarding point 2) because *E. coli* is not a representative species of all bacteria, its *fadB* is not a representative species identifying all the genes, from other bacteria, that have a similar function as *fadB* in *E. coli*. Therefore, any bacterial *fadB* gene is not described by Applicants and transformation with it is not enabled for reasons explained in rejection for lack of enablement. Furthermore, even if PHA genes are known for many bacteria, they are not known for any, i.e. all bacteria, and transformation with them requires undue experimentation for the reasons explained in rejection for the scope of enablement.

In conclusion, the rejection under 35 USC section 112, first paragraph is not withdrawn.

3. Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

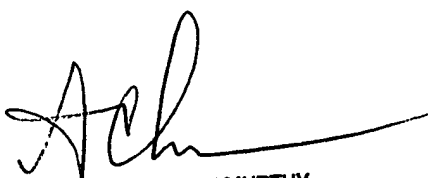
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Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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